

REMARKS

Claims 1-56 are pending in the application. Claims 17-32 and 35-56 have been withdrawn from consideration. Claims 2, 6-12 and 16 were rejected.

Claims 10-12 are being cancelled without prejudice or disclaimer. Claim 16 has been amended to specify that the treated psychosis is schizophrenia or its symptoms. Support for this amendment can be found throughout the specification and claims as originally filed, e.g., page 1, ¶ [0004]. No new matter has been introduced by this amendment.

Although the Office Action does not indicate that any claims are allowed, Applicants note that claims 1, 3-5, 13-16, 33 and 34 were not listed as having been rejected. Applicants therefore assume that these claims are allowable.

Reconsideration of the claim rejections, examination of the withdrawn claims and allowance of the pending claims, in view of the amendments above and the following remarks, are respectfully requested.

Claim Rejections – 35 U.S.C. § 112

(a) Claim 2 was rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for incorporating Fig. 1 by reference. The Examiner recommends incorporating the actual figure itself into the claims, or using the following language: “The compound of claim 1, having the X-ray diffraction pattern with characteristic peaks expressed in d-values (A) at . . .” Applicants respectfully traverse this basis for rejection.

According to MPEP § 2173.05(s):

Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience.” *Ex parte Fressola*, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Consistent with MPEP § 2173.05(s), incorporation by reference of Fig. 1 into claim 2 is necessary because 1) the X-ray diffraction pattern for amorphous ziprasidone hydrochloride, which lacks distinct characteristic peaks, cannot be adequately described

as the Examiner suggests, and 2) it is more concise than duplicating the X-ray diffraction pattern into the claim. Applicants also wish to note that incorporation by reference of X-ray diffraction patterns into patent claims is standard practice in the pharmaceutical arts. See, e.g., U.S. Patent Nos. 7,074,928, 7,060,712, 7,015,238, 6,998,503, 6,958,337 and 6,900,221. In fact, the Examiner assigned to the instant application has previously allowed claims that incorporate by reference X-ray diffraction patterns. See, e.g., U.S. Patent No. 6,852,747, claim 2. Accordingly, Applicants respectfully request reconsideration of this basis for rejection.

(b) Claims 2 and 10 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because they recite the term “substantially.” According to the Examiner, it is unclear what Applicants are intending to encompass within the claimed compound since the boundaries are not discernable. Claim 10 has been cancelled, thereby rendering moot the rejection with respect to this claim. With respect to claim 2, Applicants respectfully traverse this basis for rejection.

According to MPEP § 2173.05(b):

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

Applicants submit that, contrary to the Examiner’s position, one skilled in the art would ascertain the scope of claim 2 in light of the specification. Paragraph [0038] of the instant specification explains that variations of X-ray diffraction patterns are expected depending upon the specific diffractometer used, the analyst and the sample preparation technique. Thus, one skilled in the art of diffractometry would clearly be apprised of the scope of “substantially the same X-ray diffraction pattern as shown in Fig. 1” recited in claim 2. Accordingly, Applicants respectfully request reconsideration of this basis for rejection.

(c) Claims 6-9, 11 and 12 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because they recite the phrase “at least.” According to the Examiner, the instant specification lacks a standard for measuring the degree intended, i.e., there is no upper limit defined in the claims. Claims 11 and 12 have been cancelled, thereby rendering moot the rejection with respect to these claims. With respect to claims 6-9, Applicants respectfully traverse this basis for rejection.

Contrary to the Examiner’s position, one skilled in the art is clearly apprised of the upper limit of claims 6-9. By definition, the phrase “at least” provides for greater amounts than the recited minimum amounts of amorphous ziprasidone hydrochloride, up to 100%. The Examiner acknowledges this meaning of “at least” by stating at page 5 of the Office Action that “the claims are inclusive of any composition that contains more than the recited minimum amount.” Applicants submit that such clarity of scope is the antithesis of indefiniteness. Accordingly, Applicants respectfully request reconsideration of this basis for rejection.

(d) Claims 10-12 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite because they recite the phrase “crystalline Form I.” According to the Examiner, by merely reciting the term “Form I,” Applicants have not provided a clear definition as to what crystalline form is intended to be claimed. Claims 10-12 have been cancelled, thereby rendering moot the rejection with respect to these claims.

(e) Claim 16 was rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being fully enabled. According to the Examiner, while various psychotic or intellectual impairment diseases/disorders that may be treated by administering ziprasidone are listed on page 1 of the instant specification, the number of diseases and conditions encompassed by claim 16 is not enabled. The Examiner recommends incorporation of the specific diseases/disorders that ziprasidone is enabled for treating.

Applicants wish to point out that several patents disclose to those skilled in the art that ziprasidone has utility in, and thus enables claims for, the treatment of a wide range of psychotic disorders. See, e.g., U.S. Patent Nos. 4,831,031 and 6,245,766. In fact, claim 9 of U.S. Patent 6,150,366 is directed to a method of treating a psychosis

using a crystalline ziprasidone hydrochloride formulation. However, solely in the interest of expediting prosecution, Applicants have amended claim 16 by incorporating the disorders and symptoms listed in ¶ [0004] of the instant specification and known to be treatable by ziprasidone. Accordingly, Applicants respectfully request reconsideration of this basis for rejection.

CONCLUSION

It is believed that claims 1-9, 13-16, 33 and 34 are in condition for allowance, and an early notice of their allowability is respectfully solicited. If any minor matters remain to be resolved in this application, please contact the undersigned to arrange for a telephonic or personal interview to expedite resolution.

Respectfully submitted,

/R. A. Franks/

Robert A. Franks
Reg. No. 28,605
Attorney for Applicants

March 12, 2007

Dr. Reddy's Laboratories, Inc.
200 Somerset Corporate Blvd., Seventh Floor
Bridgewater, New Jersey 08807-2862
Telephone No.: 908-203-6504
Facsimile No.: 908-203-6515